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EXAMINER	
FEISEE	
ART UNIT	PAPER NUMBER
1806	19

DATE MAILED: 04/24/96

Below is a communication from the EXAMINER in charge of this application

COMMISSIONER OF PATENTS AND TRADEMARKS

ADVISORY ACTION

☒ THE PERIOD FOR RESPONSE:

a) ☒ ~~is extended to run~~ _____ or continues to run 3 months from the date of the final rejection

b) ☐ expires three months from the date of the final rejection or as of the mailing date of this Advisory Action, whichever is later. In no event however, will the statutory period for the response expire later than six months from the date of the final rejection.

Any extension of time must be obtained by filing a petition under 37 CFR 1.136(a), the proposed response and the appropriate fee. The date on which the response, the petition , and the fee have been filed is the date of the response and also the date for the purposes of determining the period of extension and the corresponding amount of the fee. Any extension fee pursuant to 37 CFR 1.17 will be calculated from the date of the originally set shortened statutory period for response or as set forth in b) above.

☐ Appellant's Brief is due in accordance with 37 CFR 1.192(a).

☒ Applicant's response to the final rejection, filed 4/2/96 has been considered with the following effect, but it is not deemed to place the application in condition for allowance:

1. ☐ The proposed amendments to the claim and /or specification will not be entered and the final rejection stands because:

   a. ☐ There is no convincing showing under 37 CFR 1.116(b) why the proposed amendment is necessary and was not earlier presented.

   b. ☐ They raise new issues that would require further consideration and/or search. (See Note).

   c. ☐ They raise the issue of new matter. (See Note).

   d. ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal.

   e. ☐ They present additional claims without cancelling a corresponding number of finally rejected claims.

   NOTE: _____

2. ☐ Newly proposed or amended claims _____ would be allowed if submitted in a separately filed amendment cancelling the non-allowable claims.

3. ☒ Upon the filing an appeal, the proposed amendment ☒ will be entered ☐ will not be entered and the status of the claims will be as follows:

   Claims allowed: None
   Claims objected to: None
   Claims rejected: 11, 13, 15

   However;

   ☐ Applicant's response has overcome the following rejection(s): _____

4. ☒ The affidavit, exhibit or request for reconsideration has been considered but does not overcome the rejection because the rejections are maintained. See attached discussion.

5. ☐ The affidavit or exhibit will not be considered because applicant has not shown good and sufficent reasons why it was not earlier presented.

☐ The proposed drawing correction ☐ has ☐ has not been approved by the examiner.

☐ Other

PTOL-303 (REV. 5-89)

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Applicant argues that the state of the art at the time of the invention was such that it would have been clear to one of ordinary skill that an antibody useful for diagnostic applications, ie. immunoassays would imply a pure product. Applicant refers to page 15 of the specification where it is stated that "methods for production and screening of antibodies" belied the purity of the antibodies. Applicant is referred to page 15, lines 33-36 where it is stated "For the production of hybridomas [emphasis added] secreting said monoclonal antibodies conventional production and screening methods are used." The methods of production and screening as stated in the specification are for monoclonal antibody production. The claims are directed to "purified antibodies" which are broader in scope and include polyclonal and anti-serum. As broadly claimed, the purity of the claimed antibody and the antibodies of the prior art is the same. Applicant has mischaracterized the antibodies of the reference as being a "mere needle prick away from coursing through the veins of a patient." This is clearly not what is taught in the prior art, as the antibodies of the prior art was shown to be useful in detecting the presence of the antigens found in the HIV infected patients. Even applicant's exhibit 1 at page 120 teaches the purification of anti-serum for detection.

Applicant argues that the references should be considered as product of nature,m however, the hand of man is present in the references, because the sera is isolated and are used in the detection of various antigens. For this reason the references do not merely teach HIV infected blood, rather, antisera isolated form HIV infected patients. The evidence references of Arya, Wong-Staal and Cohen were stated to show that these specificities are inherent in antisera which is isolated from an HIV infected individual. They need not teach how they would be isolated, rather that the isolated anti-sera of Kalyanaraman and Schupbach contains these specificities.

The exhibits submitted by applicant were cited to show that purification of antibodies was well known in the art. This is not in dispute, however, the degree of purity of the claimed antibodies and those in the prior art (as broadly claimed) appear to be the same. The exhibits have been considered in so far as they pertain to the rejection, however they do not comply with the IDS rules and have not been fully considered.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lila Feisee whose telephone number is (703) 308-2731. The examiner can normally be reached on Mondays-Fridays from 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marian Knode, can be reached on (703) 308-4311. The fax number for this Group is (703) 308-4065.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Lila Feisee/lf
April 22, 1996

LILA FEISEE
PRIMARY EXAMINER
GROUP 1800